UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2021.

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____ .

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
220 East First Street, Bethlehem, Pennsylvania	**18015**
(Address of Principal Executive Offices)	**(Zip code)**

Registrant's telephone number, including area code: (610) 882-1820

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.000001 par value per share	OSUR	The NASDAQ Stock Market LLC

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 1, 2021, the registrant had 72,008,941 shares of common stock, $.000001 par value per share, outstanding.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except per share amounts)

	June 30, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 158,120	$ 160,802
Short-term investments	35,185	48,599
Accounts receivable, net of allowance for doubtful accounts of $4,458 and $3,654	35,259	38,835
Inventories	48,170	31,863
Prepaid expenses	5,370	3,860
Other current assets	2,946	4,934
Total current assets	285,050	288,893
Noncurrent Assets:		
Property, plant and equipment, net	72,034	51,860
Operating right-of-use assets, net	10,140	4,461
Finance right-of-use assets, net	2,484	1,312
Intangible assets, net	16,241	17,904
Goodwill	40,810	40,351
Long-term investments	36,131	47,718
Other noncurrent assets	2,159	1,973
Total noncurrent assets	179,999	165,579
TOTAL ASSETS	**$ 465,049**	**$ 454,472**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 22,119	$ 17,407
Deferred revenue	4,240	4,811
Accrued expenses and other current liabilities	16,899	22,227
Finance lease liability	1,017	517
Operating lease liability	2,078	1,125
Acquisition-related contingent consideration obligation	219	402
Total current liabilities	46,572	46,489
Noncurrent Liabilities:		
Finance lease liability	1,569	895
Operating lease liability	8,274	3,591
Acquisition-related contingent consideration obligation	800	2,049
Other noncurrent liabilities	2,010	1,682
Deferred income taxes	1,008	1,195
Total noncurrent liabilities	13,661	9,412
TOTAL LIABILITIES	60,233	55,901
Commitments and contingencies (Note 11)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value $.000001, 120,000 shares authorized, 72,008 and 71,738 shares issued and outstanding	—	—
Additional paid-in capital	506,304	505,123
Accumulated other comprehensive loss	(6,443)	(9,097)
Accumulated deficit	(95,045)	(97,455)
Total stockholders' equity	404,816	398,571
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 465,049**	**$ 454,472**

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
NET REVENUES:				
Products and services	$ 55,741	$ 28,337	$ 112,320	$ 59,223
Other	1,866	922	3,869	1,632
	57,607	29,259	116,189	60,855
COST OF PRODUCTS AND SERVICES SOLD	26,934	11,995	47,190	27,460
Gross profit	30,673	17,264	68,999	33,395
OPERATING EXPENSES:				
Research and development	7,682	6,924	16,674	12,568
Sales and marketing	10,420	10,121	19,950	17,490
General and administrative	10,993	10,280	21,181	20,334
Change in the estimated fair value of acquisition-related contingent consideration	(220)	(660)	(1,026)	450
	28,875	26,665	56,779	50,842
Operating income (loss)	1,798	(9,401)	12,220	(17,447)
OTHER INCOME	448	216	329	1,646
Income (loss) before income taxes	2,246	(9,185)	12,549	(15,801)
INCOME TAX EXPENSE	3,610	1,309	10,139	2,021
NET INCOME (LOSS)	$ (1,364)	$ (10,494)	$ 2,410	$ (17,822)
INCOME (LOSS) PER SHARE:				
BASIC	$ (0.02)	$ (0.16)	$ 0.03	$ (0.28)
DILUTED	$ (0.02)	$ (0.16)	$ 0.03	$ (0.28)
SHARES USED IN COMPUTING INCOME (LOSS) PER SHARE:				
BASIC	71,983	64,745	71,931	63,335
DILUTED	71,983	64,745	72,683	63,335

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(Unaudited)
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
NET INCOME (LOSS)	$ (1,364)	$ (10,494)	$ 2,410	$ (17,822)
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	1,403	3,726	2,755	(5,495)
Unrealized gain (loss) on marketable securities	(122)	791	(101)	349
COMPREHENSIVE INCOME (LOSS)	$ (83)	$ (5,977)	$ 5,064	$ (22,968)

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2021	**2020**
OPERATING ACTIVITIES:		
Net income (loss)	$ 2,410	$ (17,822)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	2,937	4,048
Depreciation and amortization	5,144	4,494
Other non-cash amortization	380	106
Provision for doubtful accounts	747	1,365
Unrealized foreign currency (gain) loss	(364)	5
Interest expense on finance leases	35	39
Deferred income taxes	(218)	(146)
Change in the estimated fair value of acquisition-related contingent consideration	(1,026)	450
Payment of acquisition-related contingent consideration	(142)	(496)
Changes in assets and liabilities		
Accounts receivable	3,680	9,311
Inventories	(16,065)	(4,693)
Prepaid expenses and other assets	154	369
Accounts payable	4,400	(605)
Deferred revenue	(630)	1,311
Accrued expenses and other liabilities	(4,914)	80
Net cash used in operating activities	(3,472)	(2,184)
INVESTING ACTIVITIES:		
Purchases of investments	(10,428)	(66,309)
Proceeds from maturities and redemptions of investments	43,745	87,616
Purchases of property and equipment	(22,929)	(6,037)
Proceeds from escrow associated with business acquisitions	—	126
Purchase price adjustment related to business acquisition	(18)	—
Purchase of patent and product rights	—	(2,250)
Net cash provided by investing activities	10,370	13,146
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(510)	(354)
Payment of acquisition-related contingent consideration	(264)	(3,004)
Issuance of common stock in connection with public offering, net	—	95,036
Proceeds from exercise of stock options	121	560
Repurchase of common stock	(1,877)	(2,064)
Net cash (used in) provided by financing activities	(2,530)	90,174
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(7,050)	(2,977)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,682)	98,159
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	160,802	75,715
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 158,120	$ 173,874
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 10,329	$ 1,557
Non-cash investing and financing activities		
Accrued property and equipment purchases	$ 896	$ 704
Unrealized gain (loss) on marketable securities	$ (101)	$ 349

See accompanying notes to the consolidated financial statements.

1. The Company

The overall goal of OraSure Technologies, Inc. (“OraSure” or “the Company”) is to empower the global community to improve health and wellness by providing access to accurate essential information. Our business consists of two segments: our “Diagnostics” segment, and our “Molecular Solutions” segment.

Our Diagnostics business primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. The Diagnostics business includes tests for diseases including HIV and Hepatitis C that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. Our HIV product is also sold in a consumer-friendly format in the over-the-counter (“OTC”) market in the U.S. and as a self-test to individuals in a number of other countries. Our Diagnostics business includes the operations of UrSure, Inc. (“UrSure”), which was acquired and merged into OraSure in 2020. This part of the Diagnostics business develops and commercializes products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV, and anti-retroviral medications to suppress HIV. These products include laboratory-based tests that can measure levels of the medications in a patient’s urine or blood, as well as point-of-care products currently in development. In 2020, we began developing a rapid antigen self-test for COVID-19 and a COVID-19 antibody enzyme-linked immunosorbent assay (“ELISA”) for use in laboratory settings. In June 2021, we received three Emergency Use Authorizations ("EUA") from the U.S. Food and Drug Administration ("FDA") for our InteliSwab™ COVID-19 Rapid Antigen Tests for non-prescription over-the-counter ("OTC"), professional point-of-care and prescription use. Following discussions with the FDA and their de-prioritization of antibody testing in the U.S., we have decided to no longer pursue EUAs for the ELISA test. We will, however, continue to offer the product for research use only to labs and other parties interested in COVID antibody surveillance and research applications.

Our Molecular Solutions business is operated by our subsidiaries, DNA Genotek Inc. (“DNAG”), Diversigen, Inc. (“Diversigen”), and Novosanis NV (“Novosanis”). In our DNAG business, we manufacture and sell kits that are used to collect, stabilize, transport and store a biological sample of genetic material for molecular testing. Our products are used for academic research and commercial applications, including ancestry, disease risk management, lifestyle and animal testing. Three of our collection devices are used in connection with COVID-19 molecular testing. We also sell research-use-only collection products into the microbiome market. We offer our customers a suite of genomics and microbiome services that range from package customization and study design optimization to extraction, analysis and reporting services. The microbiome laboratory and bioinformatics services are provided by Diversigen, which includes the operations of CoreBiome, Inc. (“CoreBiome”), a subsidiary we acquired in early 2019. CoreBiome and Diversigen were merged together in 2020. Novosanis manufactures and sells the Colli-Pee® collection device for the volumetric collection of first-void urine for use in research, screening and diagnostics in the liquid biopsy and sexually transmitted infection markets. Our Molecular Solutions business serves customers in many countries worldwide, including many leading research universities and hospitals.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation. The accompanying interim unaudited consolidated financial statements include the accounts of OraSure and its wholly-owned subsidiaries, DNAG, Diversigen and Novosanis. All intercompany transactions and balances have been eliminated. References herein to “we,” “us,” “our,” or the “Company” mean OraSure and its consolidated subsidiaries, unless otherwise indicated. The unaudited financial statements, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020. Results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results of operations expected for the full year.

Summary of Significant Accounting Policies. There have been no changes to the Company's significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 that have had a material impact on the consolidated financial statements and related notes except as discussed herein.

Investments. We consider all investments in debt securities to be available-for-sale securities. These securities consist of guaranteed investment certificates and corporate bonds with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders' equity as a component of accumulated other comprehensive loss.

We record an allowance for credit loss for our available-for-sale securities when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, we review factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, the Company's intent to sell or the likelihood that it would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. As of June 30, 2021, we determined that the decline in the market value of our available-for-sale investment was not due to credit-related factors and as such no allowance for credit-loss was necessary.

The following is a summary of our available-for-sale securities as of June 30, 2021 and December 31, 2020:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2021				
Guaranteed investment certificates	$ 33,874	$ —	$ —	$ 33,874
Corporate bonds	37,891	31	(480)	37,442
Total available-for-sale securities	$ 71,765	$ 31	$ (480)	$ 71,316
December 31, 2020				
Guaranteed investment certificates	$ 25,132	$ —	$ —	$ 25,132
Corporate bonds	71,533	135	(483)	71,185
Total available-for-sale securities	$ 96,665	$ 135	$ (483)	$ 96,317
At June 30, 2021, maturities of our available-for-sale securities were as follows:				
Less than one year	$ 35,567	$ 31	$ (413)	$ 35,185
Greater than one year	$ 36,198	$ —	$ (67)	$ 36,131

Fair Value of Financial Instruments. As of June 30, 2021 and December 31, 2020, the carrying values of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate their respective fair values based on their short-term nature.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

All of our available-for-sale debt securities are measured as Level 2 instruments as of June 30, 2021 and December 31, 2020. Our available-for-sale guaranteed investment certificates are measured as Level 1 instruments as of June 30, 2021 and December 31, 2020.

Included in cash and cash equivalents at June 30, 2021 and December 31, 2020, was $53,590 and $71,489 invested in government money market funds. These funds have investments in government securities and are measured as Level 1 instruments.

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds. The fair value of the plan assets as of June 30, 2021 and December 31, 2020 was $2,486 and $2,565, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in both current assets and noncurrent assets with the same amount included in accrued expenses and other noncurrent liabilities in the accompanying consolidated balance sheets.

Accounts Receivable. Accounts receivable have been reduced by an estimated allowance for amounts that may become uncollectible in the future. This estimated allowance is based primarily on management's evaluation of specific balances as they become past due, the financial condition of our customers and our historical experience related to write-offs.

Inventories. Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating, which can be extended in certain circumstances. We continually evaluate quantities on hand and the carrying value of our inventories to determine the need for reserves for excess and obsolete inventories, based on prior experience as well as estimated forecasts of product sales. We reserve for unidentified scrap or spoilage based on historical write-off rates. We also consider items identified through specific identification procedures in assessing the adequacy of our reserve. When factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off, as in the case of lapsing expiration dates.

Property, Plant and Equipment. Property, plant and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold, retired, or discarded, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statements of operations. Accumulated depreciation of property, plant and equipment as of June 30, 2021 and December 31, 2020 was $56,992 and $53,604, respectively.

Intangible Assets. Intangible assets consist of customer relationships, patents and product rights, acquired technology and tradenames. Patents and product rights consist of costs associated with the acquisition of patents, licenses, and product distribution rights. Intangible assets are amortized using the straight-line method over their estimated useful lives of five to fifteen years. Accumulated amortization of intangible assets as of June 30, 2021 and December 31, 2020 was $29,237 and $27,107, respectively. The decrease in intangibles from $17,904 as of December 31, 2020 to $16,241 as of June 30, 2021 is due to $1,643 in amortization expense and foreign currency translation losses of $20.

Goodwill. Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current generally accepted accounting principles ("GAAP") permit us to make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the carrying value of a reporting unit is greater than its fair value, then we would be required to recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

The increase in goodwill from $40,351 as of December 31, 2020 to $40,810 as of June 30, 2021 is a result of an adjustment of $441 associated with foreign currency translation and a purchase price adjustment of $18 related to a business acquisition.

Foreign Currency Translation. The assets and liabilities of our foreign operations are translated into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than a functional currency are included in our consolidated statements of income in the period in which the change occurs. Net foreign exchange gains (losses) resulting from foreign currency transactions that are included in other income in our consolidated statements of income were $198 and $(200) for the three months ended June 30, 2021 and 2020, respectively. Net foreign exchange gains (losses) were $(379) and $493 for the six months ended June 30, 2021 and 2020.

Accumulated Other Comprehensive Income (Loss). We classify items of other comprehensive income (loss) by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of our consolidated balance sheets.

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and we have defined the Euro as the functional currency of our Belgian subsidiary, Novosanis. The results of operations for those subsidiaries are translated into U.S. dollars, which is the reporting currency of the Company. Accumulated other comprehensive loss at June 30, 2021 consists of $5,994 of currency translation adjustments and $449 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our investment portfolio. Accumulated other comprehensive loss at December 31, 2020 consists of $8,749 of currency translation adjustments and $348 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our investments portfolio.

Recent Accounting Pronouncements.

In March 2020, the FASB issued Accounting Standards Update ("ASU") No. 2020-04, *Reference Rate Reform* (Topic 848) Facilitation of the Effects of Reference Rate Reform on Financial Reporting. The purpose of this update is to provide optional guidance for a limited time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. The amendments provide optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The amendments in this update are elective and are effective upon issuance for all entities. Management is evaluating the impact of this ASU and does not expect this update to have a material impact on the Company's Consolidated Financial Statements.

3. Business Combinations

UrSure

On July 22, 2020, the Company acquired all of the outstanding capital stock of UrSure, Inc. ("UrSure"), pursuant to the terms of a merger agreement. The initial aggregate purchase price of this transaction was $3,000, adjusted for certain transaction costs, indebtedness, and holdback amounts, and was funded with cash on hand. A portion of the purchase price was deposited into an escrow account for a limited period after closing, pursuant to indemnification obligations under the merger agreement.

During the six months ended June 30, 2020, we incurred acquisition related costs of $343 including accounting, legal, and other professional fees, all of which were expensed and reported as a component of general and administrative expense in the consolidated statement of operations. No such costs were incurred for the six months ended June 30, 2021.

Pursuant to our merger agreement, we may pay up to an additional $28,000 of contingent consideration over the next three years based on the achievement of certain performance criteria as defined under the agreements, including generating certain revenue dollars, and the achievement of certain clinical milestones associated with the development of certain new technology. The Company, with the assistance of an independent valuation specialist, determines the estimated fair value of the contingent consideration. The fair value is determined using a probability-weighted model based on our assessment of the likelihood that the benchmarks will be achieved. The probability-weighted payments were then discounted using a discount rate based on an internal rate of return analysis using the probability-weighted cash flows. The fair value measurement is based on significant inputs, including the likelihood of the achievement of clinical milestones and revenue forecasts, not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy.

The following table represents the change in contingent consideration:

Balance as of December 31, 2020	$	2,451
Payments made during the period		(406)
Change in fair value during the period		(1,026)
Balance as of June 30, 2021	$	1,019

Revenues from UrSure primarily consist of grant money received to fund the development of certain new technology. Effective as of July 22, 2020, the financial results of UrSure are included in our Diagnostics segment.

4. Inventories

	June 30, 2021	December 31, 2020
Raw materials	$ 21,896	$ 15,425
Work in process	3,287	2,572
Finished goods	22,987	13,866
	$ 48,170	$ 31,863

5. Earnings (Loss) Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted-average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options, unvested restricted stock or performance stock units, unless the impact is antidilutive. The number of incremental

shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares and performance stock units were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market price during the reporting period. Basic and dilutive computations of net loss per share are the same in periods in which a net loss exists as the dilutive effects of excluded items would be anti-dilutive.

The computations of basic and diluted earnings (loss) per share are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net income (loss)	$ (1,364)	$ (10,494)	$ 2,410	$ (17,822)
Weighted-average shares of common stock outstanding:				
Basic	71,983	64,745	71,931	63,335
Dilutive effect of stock options, restricted stock, and performance stock units	—	—	752	—
Diluted	71,983	64,745	72,683	63,335
Earnings (loss) per share:				
Basic	$ (0.02)	$ (0.16)	$ 0.03	$ (0.28)
Diluted	$ (0.02)	$ (0.16)	$ 0.03	$ (0.28)

For the three months ended June 31, 2021 and 2020, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 603 and 1,078 shares, respectively, were excluded from the computation of diluted loss per share. For the six months ended June 30, 2021, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 604 shares were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the six months ended June 30, 2020, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 704 shares were excluded from the computation of diluted loss per share.

6. Revenues

Revenues by product. The following table represents total net revenues by product line:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Infectious disease testing	$ 15,534	$ 8,737	$ 26,732	$ 23,400
Risk assessment testing	2,629	1,533	4,591	4,533
Genomics	19,582	6,471	30,646	14,863
Microbiome	2,853	853	4,941	2,430
COVID-19	11,580	8,472	39,142	8,866
Laboratory services	3,114	2,103	5,611	4,517
Other product and service revenues	449	168	657	614
Net product and services revenues	55,741	28,337	112,320	59,223
Royalty income	875	727	2,136	1,172
Other non-product revenues	991	195	1,733	460
Other revenues	1,866	922	3,869	1,632
Net revenues	$ 57,607	$ 29,259	$ 116,189	$ 60,855

Revenues by geographic area. The following table represents total net revenues by geographic area, based on the location of the customer:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
United States	$ 47,601	$ 21,912	$ 96,700	$ 43,528
Europe	3,325	3,069	7,877	5,874
Other regions	6,681	4,278	11,612	11,453
	$ 57,607	$ 29,259	$ 116,189	$ 60,855

Customer and Vendor Concentrations. We had no significant customer concentrations (greater than 10%) in our accounts receivable at June 30, 2021. One of our customers accounted for 11% of our accounts receivable as of December 31, 2020. One customer accounted for 14% of net consolidated revenues for the three months ended June 30, 2021. Another customer accounted for 10% and 14%, respectively, of net consolidated

revenues for the three and six months ended June 30, 2021. We had no significant customer concentrations (greater than 10%) in our net consolidated revenues for the three months and six months ended June 30, 2020.

We currently purchase certain products and critical components of our products from sole-supply vendors. If these vendors are unable or unwilling to supply the required components and products, we could be subject to increased costs and substantial delays in the delivery of our products to our customers. Third-party suppliers also manufacture certain products. Our inability to have a timely supply of any of these components and products could have a material adverse effect on our business, as well as our financial condition and results of operations.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of June 30, 2021 and December 31, 2020 includes customer prepayments of $2,884 and $3,216, respectively. Deferred revenue as of June 30, 2021 and December 31, 2020 also includes $1,356 and $1,595, respectively, associated with a long-term contract that has variable pricing based on volume. The average price over the life of the contract was determined and revenue is recognized at that average price.

7. Accrued Expenses and other current liabilities

	June 30, 2021	December 31, 2020
Payroll and related benefits	$ 9,905	$ 14,769
Professional fees	1,196	978
Sales tax payable	2,843	2,400
Other	2,955	4,080
	$ 16,899	$ 22,227

8. Leases

We determine whether an arrangement is a lease at inception. We have operating and finance leases for corporate offices, warehouse space and equipment (including vehicles). As of June 30, 2021, we are the lessee in all agreements. Our leases have remaining lease terms of 1 to 7 years, some of which include options to extend the leases based on agreed upon terms, and some of which include options to terminate the leases within 1 year.

As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

We have lease agreements that contain both lease and non-lease components (e.g., common-area maintenance). For these agreements, we account for lease components separate from non-lease components.

The components of lease expense are as follows:

	Three Months Ended		Six Months Ended	
	2021	2020	2021	2020
Operating Lease Cost	$ 499	$ 322	$ 919	$ 634
Finance Lease Cost				
Amortization of right-of use assets	212	163	339	326
Interest on lease liabilities	21	19	35	39
Total Finance Lease Cost	$ 233	$ 182	$ 374	$ 365

Supplemental cash flow information related to leases is as follows:

	Three Months Ended		Six Months Ended	
	2021	2020	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	$ 416	$ 314	$ 824	$ 630
Operating cash flows from financing leases	21	19	35	39
Financing cash flows from financing leases	228	179	510	354
Non-cash activity:				
Right-of-use assets obtained in exchange for operating lease obligations	7,205	—	7,834	498
Right-of-use assets obtained in exchange for finance lease obligations	—	—	—	46

Supplemental balance sheet information related to leases is as follows:

	June 30, 2021	December 31, 2020
Operating Leases		
Right-of-use assets	$ 10,140	$ 4,461
Current lease liabilities	2,078	1,125
Non-current lease liabilities	8,274	3,591
Total operating lease liabilities	$ 10,352	$ 4,716
Finance Leases		
Right-of-use assets	$ 2,484	$ 1,312
Current lease liabilities	1,017	517
Non-current lease liabilities	1,569	895
Total finance lease liabilities	$ 2,586	$ 1,412

Weighted Average Remaining Lease Term	
Weighted-average remaining lease term—operating leases	5.60
Weighted-average remaining lease term—finance leases	2.55
Weighted Average Discount Rate	
Weighted-average discount rate—operating leases	3.61%
Weighted-average discount rate—finance leases	3.75%

As of June 30, 2021, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2021 (excluding the six months ended June 30, 2021)	$ 547	$ 1,178
2022	1,094	2,472
2023	864	1,777
2024	201	1,809
2025	4	1,444
Thereafter	—	2,810
Total Minimum Lease Payments	2,710	11,490
Less: imputed interest	(124)	(1,138)
Present Value of Lease Liabilities	$ 2,586	$ 10,352

9. Stockholders' Equity

Reconciliation of the changes in stockholders' equity for the three and six months ended June 30, 2021 and 2020

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2020	71,738	$ —	$ 505,123	$ (9,097)	$ (97,455)	$ 398,571
Common stock issued upon exercise of options	11	—	92	—	—	92
Vesting of restricted stock and performance stock units	318	—		—	—	—
Purchase and retirement of common shares	(111)	—	(1,730)	—	—	(1,730)
Stock-based compensation	—	—	1,464	—	—	1,464
Net income	—	—	—	—	3,774	3,774
Currency translation adjustments	—	—	—	1,352	—	1,352
Unrealized gain on marketable securities	—	—	—	21	—	21
Balance at March 31, 2021	71,956	$ —	$ 504,949	$ (7,724)	$ (93,681)	$ 403,544
Common stock issued upon exercise of options	3	—	29	—	—	29
Vesting of restricted stock and performance stock units	64	—	—	—	—	—
Purchase and retirement of common shares	(15)	—	(147)	—	—	(147)
Stock-based compensation	—	—	1,473	—	—	1,473
Net loss	—	—	—	—	(1,364)	(1,364)
Currency translation adjustments	—	—	—	1,403	—	1,403
Unrealized loss on marketable securities	—	—	—	(122)	—	(122)
Balance at June 30, 2021	72,008	$ —	$ 506,304	$ (6,443)	$ (95,045)	$ 404,816

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2019	61,731	$ —	$ 401,814	$ (12,136)	$ (82,533)	$ 307,145
Common stock issued upon exercise of options	6	—	30	—	—	30
Vesting of restricted stock and performance stock units	486	—	—	—	—	—
Purchase and retirement of common shares	(197)	—	(1,408)	—	—	(1,408)
Stock-based compensation	—	—	1,376	—	—	1,376
Net loss	—	—	—	—	(7,328)	(7,328)
Currency translation adjustments	—	—	—	(9,221)	—	(9,221)
Unrealized loss on marketable securities	—	—	—	(442)	—	(442)
Balance at March 31, 2020	62,026	$ —	$ 401,812	$ (21,799)	$ (89,861)	$ 290,152
Common stock issued upon exercise of options	71	—	530	—	—	530
Vesting of restricted stock and performance stock units	161	—	—	—	—	—
Purchase and retirement of common shares	(50)	—	(656)	—	—	(656)
Issuance of common stock in connection with public offering, net of commissions and expenses of $6,200	9,200		95,036			95,036
Stock-based compensation	—	—	2,672	—	—	2,672
Net loss	—	—	—	—	(10,494)	(10,494)
Currency translation adjustments	—	—	—	3,726	—	3,726
Unrealized gain on marketable securities	—	—	—	791	—	791
Balance at June 30, 2020	71,408	$ —	$ 499,394	$ (17,282)	$ (100,355)	$ 381,757

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended (the "Stock Plan"). The Stock Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the Stock Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards. We account for stock-based compensation to employees and directors using the fair value method. We recognize compensation expense for stock option and restricted stock awards issued to employees and directors on a straight-line basis over the requisite service period of the award. We recognize compensation expense related to performance-based restricted stock units based on assumptions as to what percentage of each performance target will be achieved. We evaluate these target assumptions on a quarterly basis and adjust compensation expense related to these awards, as appropriate. To satisfy the exercise of options, issuance of restricted stock, or redemption of performance-based restricted stock units, we issue new shares rather than shares purchased on the open market.

Total compensation cost related to stock options for the six months ended June 30, 2021 and 2020 was $521 and $468 respectively.

Compensation cost of $2,066 and $2,556 related to restricted shares was recognized during the six months ended June 30, 2021 and 2020, respectively.

We grant performance-based restricted stock units ("PSUs") to certain executives. Vesting of these PSUs is dependent upon achievement of performance-based metrics during a one-year or three-year period from the date of grant. Assuming achievement of each performance-based metric, the executive must also generally remain employed for three years from the grant date. Performance during the one-year period is based on a one-year income before income taxes target. If the one-year target is achieved, the PSUs will then vest three years from grant date. Performance during the three-year period will be based on achievement of a three-year compound annual growth rate for consolidated product revenues. If the three-year target is achieved, the corresponding PSUs will then vest three years from grant date. PSUs are converted into shares of our common stock once vested.

Compensation cost of $350 and $1,024 related to PSUs was recognized during the six months ended June 30, 2021 and 2020, respectively.

Public Offering

On June 1, 2020, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Evercore Group LLC, as representatives of several underwriters, relating to the issuance and sale of 8,000 shares of our common stock. The price to the public in the offering was $11.00 per share. Under the terms of the underwriting agreement, we also granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,200,000 shares of common stock. On June 3, 2020, we announced the full exercise by the underwriters of their option to purchase these additional shares.

The offering was made pursuant to an effective registration statement on Form S-3 (File No. 333-228877) we had previously filed with the SEC, and a prospectus supplement thereunder. The net proceeds from the offering were approximately $95,000 after deducting underwriting discounts and offering expenses paid by the Company.

Stock Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25,000 of our outstanding common shares. No shares were purchased and retired during the six months ended June 30, 2021 and 2020.

10. Income Taxes

During the three and six months ended June 30, 2021, we recorded income tax expense of $3,610 and $10,139 which primarily consists of foreign tax expense. During the three and six months ended June 30, 2020, we recorded income tax expense of $1,309 and $2,021, which also primarily consists of a foreign tax expense.

Tax expense reflects taxes due to the taxing authorities and the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liability as of June 30, 2021 and December 31, 2020 relate to the tax effects of the basis difference between the intangible assets acquired in our acquisitions for financial reporting and for tax purposes along with basis differences arising from accelerated tax depreciation of fixed assets.

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate at both June 30, 2021 and December 31, 2020 since the facts and circumstances necessitating the allowance have not changed.

11. Commitments and Contingencies

Litigation

From time to time, we are involved in certain legal actions arising in the ordinary course of business. In management's opinion, the outcomes of such actions, either individually or in the aggregate, are not expected to have a material adverse effect on our future financial position or results of operations.

In March 2021, we filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain DNA saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum has filed an answer to the initial complaint, asserting that its device does not infringe our patent and that our patent is invalid. In August 2021, we amended our complaint to add a second patent to this litigation. We are seeking injunctive relief and damages in this matter.

Commitments

As of June 30, 2021 we entered in several new contracts associated with the manufacture and supply of our COVID-19 antigen product which include certain minimum purchase commitments over the next five years as follows:

2021	$	3,441
2022		3,208
2023		3,208
2024		3,208
2025		660
	$	13,725

12. Business Segment Information

Our business consists of two segments: our "Diagnostics" business, which primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. Our Diagnostics segment includes the financial results of UrSure. Our "Molecular Solutions" business consists of the development, manufacture, marketing and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing. Our collection kits are also used for the collection of first-void urine for liquid biopsy in the prostate and bladder cancer markets; and in the sexually transmitted infection screening market. In addition, our Molecular Solutions business provides microbiome laboratory services that accelerate research and discovery for customers in the pharmaceutical, agricultural, and academic research markets. Financial results of Diversigen and Novosanis are included in our Molecular Solutions segment.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating income. We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues and inter-segment expenses have been eliminated.

The following table summarizes operating segment information for the three and six months ended June 30, 2021 and 2020, and asset information as of June 30, 2021 and December 31, 2020:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net revenues:				
Diagnostics	$ 19,311	$ 10,427	$ 33,857	$ 28,219
Molecular Solutions	38,296	18,832	82,332	32,636
Total	$ 57,607	$ 29,259	$ 116,189	$ 60,855
Operating income (loss):				
Diagnostics	$ (11,925)	$ (13,523)	$ (24,117)	$ (21,165)
Molecular Solutions	13,723	4,122	36,337	3,718
Total	$ 1,798	$ (9,401)	$ 12,220	$ (17,447)
Depreciation and amortization:				
Diagnostics	$ 939	$ 886	$ 1,829	$ 1,608
Molecular Solutions	1,716	1,517	3,315	2,886
Total	$ 2,655	$ 2,403	$ 5,144	$ 4,494
Capital expenditures:				
Diagnostics	$ 8,513	$ 2,630	$ 16,150	$ 3,448
Molecular Solutions	3,355	812	6,779	2,589
Total	$ 11,868	$ 3,442	$ 22,929	$ 6,037

	June 30, 2021	December 31, 2020
Total assets:		
Diagnostics	$ 220,373	$ 242,613
Molecular Solutions	244,676	211,859
Total	$ 465,049	$ 454,472

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings, losses, expenses, or other financial performance, future product performance or development, expected regulatory filings and approvals, planned business transactions, expected manufacturing performance, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include words such as "believes," "expects," "anticipates," "intends," "plans," "estimates," "may," "will," "should," "could," or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the U.S. Food and Drug Administration ("FDA") or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collection products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in our Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2020, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this Report, and we undertake no duty to update these statements.

Investors should also be aware that while we do, from time to time, communicate with securities analysts, it is against our policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

The following discussion should be read in conjunction with our consolidated financial statements contained herein and the notes thereto, along with the Section entitled "Critical Accounting Policies and Estimates," set forth below.

Overview and Business Segments

The overall goal of our Company is to empower the global community to improve health and wellness by providing access to accurate essential information. Our business consists of two segments: our “Diagnostics” segment and our “Molecular Solutions” segment.

Our Diagnostics business primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. The Diagnostics business includes tests for diseases including HIV and Hepatitis C that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. Our HIV product is also sold in a consumer-friendly format in the OTC market in the U.S. and as a self-test to individuals in a number of other countries. Our Diagnostics business includes the operations of UrSure, which was acquired and merged into OraSure in 2020. This part of the Diagnostics business develops and commercializes products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV, and anti-retroviral medications to suppress HIV. These products include laboratory-based tests that can measure levels of the medication in a patient’s urine or blood, as well as point- of-care products currently in development.

Our Molecular Solutions business is operated by our subsidiaries, DNAG, Diversigen and Novosanis. In this business, we manufacture and sell kits that are used to collect, stabilize, transport and store a biological sample of genetic material for molecular testing. Our products are used for academic research and commercial applications, including ancestry, disease risk management, lifestyle and animal testing. Included in the disease risk management area are pharmacogenomics testing, hereditary disease screening, prenatal or cancer screening, population health initiatives and other molecular testing using DNA or RNA for diagnosis of acute disease. We also sell research-use-only collection products into the microbiome market. We offer our customers a suite of genomics and microbiome services that range from package customization and study design optimization to extraction, analysis and reporting services. The microbiome laboratory and bioinformatics services are provided by Diversigen, which includes the operations of CoreBiome, a subsidiary we acquired in early 2019. CoreBiome and Diversigen were merged together in 2020. Novosanis manufactures and sells the Colli-Pee® collection device for the volumetric collection of first-void urine for use in research, screening and diagnostics in the liquid biopsy and sexually transmitted infection markets. Our Molecular Solutions business serves customers in many countries worldwide, including many leading research universities and hospitals.

Recent Developments

Impact of COVID-19

The COVID-19 pandemic continues to impact our business operations and it is not possible for us to predict the duration or magnitude of the outbreak’s effects on our business or results of operations. During 2020, traditional HIV and HCV testing programs and drug testing in the workplace market were reduced or terminated as a result of the various “stay-at-home” orders and social distancing guidelines issued by federal, state and local governments to contain the spread of the COVID-19 pandemic and we continued to see this impact our business in early 2021. However, during the second quarter of 2021, we began to see a resumption of HIV and HCV testing in the U.S. as domestic sales of our non-COVID diagnostic products began returning to pre-pandemic levels. On the international front, while professional HIV and HCV testing in Europe and Asia also started to pick up, more recently, we have experienced some reduction and stoppages of HIV self-testing in Southern and Eastern African countries due to the COVID-19 pandemic. In our molecular segment, COVID-related disruption in clinical and research work, particularly in the academic market, had reduced demand for our products in 2020 and early 2021, but demand levels started to return to normal in the second quarter of 2021. Although the negative trends that materially impacted our results of operations during 2020 and early 2021 are starting to abate, it is impossible to predict if this improvement will continue and these negative trends may adversely impact certain parts of our business in future periods and for an indeterminate time period, depending on the duration and severity of the COVID-19 pandemic, the impact of COVID-19 variants and the scope and success of vaccination programs globally.

We also have experienced significant opportunities, and continue to believe there are potentially more significant opportunities, for increased revenues as a result of the COVID-19 pandemic. In 2020, we began selling our saliva collection devices for use in molecular COVID-19 testing. In the first half of 2021, we generated revenues of approximately $38.9 million from sales of our molecular collection devices related to COVID-19 testing. In the U.S., public health customers purchased increased quantities of our OraQuick® In-Home HIV Test in order to permit continued HIV testing while allowing clients and patients to adhere to “stay-at-home” and social distancing requirements. In addition, we saw increased demand for our molecular collection products from customers who conduct both saliva and blood-based testing. As it becomes more difficult to collect blood in clinics or healthcare settings, these customers are increasingly relying on the saliva collection alternative. However, demand for molecular COVID-19 testing during the second quarter of 2021 began to decline primarily due to the availability of vaccines. This trend is expected to continue in future periods.

In June 2021, we received three Emergency Use Authorizations ("EUAs") from the U.S. Food and Drug Administration ("FDA") for our InteliSwab™ COVID-19 Rapid Tests for non-prescription over-the-counter ("OTC"), professional point-of-care and prescription use. These

lateral flow, rapid diagnostic tests are designed to detect active COVID-19 infection with a simple, easy-to-use workflow, using samples self-collected from the lower nostrils. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution. No instrumentation, batteries, smart phone or laboratory analysis is needed to read the result, which appears on the test stick a short time later. Because of the timing of EUA receipt and the time needed to implement final labeling for these tests, we did not report any sales of InteliSwab™ in the second quarter of 2021 and expect sales to begin in the third quarter.

Following discussions with the FDA and their de-prioritization of antibody testing in the U.S. we have decided to no longer pursue EUAs for a COVID-19 antibody enzyme-linked immunosorbent assay ("ELISA") for use in laboratory settings. We will, however, continue to offer this product for research use only to labs and other parties interested in COVID antibody surveillance and research applications.

Current Consolidated Financial Results

During the six months ended June 30, 2021, our consolidated net revenues increased 91% to $116.2 million, compared to $60.9 million for the six months ended June 30, 2020. Net product and services revenues during the six months ended June 30, 2021 increased 90% when compared to the same period of 2020, due to higher sales of our molecular sample collection kits for COVID-19 testing, commercial genomics products, microbiome kits, domestic OraQuick® HIV tests and domestic and international OraQuick® HVC tests and higher revenues from laboratory services. Partially offsetting these increases were lower sales of our international OraQuick® HIV Self-Tests. Other revenues for the six months ended June 30, 2021 were $3.9 million compared to $1.6 million in the same period of 2020. This increase was largely due to increased research and development funding for the development of our COVID-19 tests and our HIV medication adherence tests and higher royalty income.

Our consolidated net income for the six months ended June 30, 2021 was $2.4 million, or $0.03 per share on a fully diluted basis, compared to a consolidated net loss of $17.8 million, or $0.28 per share on a fully diluted basis, for the six months ended June 30, 2020. Results for the six months ended June 30, 2021 included an $1.0 million non-cash pre-tax benefit associated with the change in the fair value of acquisition-related contingent consideration which accounted for approximately $0.01 per share. Results for the six months ended June 30, 2020 included a $450,000 non-cash pre-tax charge associated with the change in the fair value of acquisition-related contingent consideration and $343,000 of acquisition related transaction costs associated with the UrSure acquisition, which together accounted for approximately $0.01 per share.

Cash used in operating activities during the six months ended June 30, 2021 and 2020 was $3.5 million and $2.2 million, respectively. As of June 30, 2021, we had $229.4 million in cash, cash equivalents, and available-for-sale securities, compared to $257.1 million at December 31, 2020.

Results of Operations

Three months ended June 30, 2021 compared to June 30, 2020

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments during the three months ended June 30, 2021 and 2020.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2021	2020	% Change	2021	2020
Diagnostics	$ 18,252	$ 10,270	78 %	32 %	35 %
Molecular Solutions	37,489	18,067	107	65	62
Net product and services revenues	55,741	28,337	97	97	97
Other	1,866	922	102	3	3
Net revenues	$ 57,607	$ 29,259	97 %	100 %	100 %

Consolidated net product and services revenues increased 97% to $55.7 million for the three months ended June 30, 2021 from $28.3 million for the three months ended June 30, 2020. All net product and service revenues in each of our business segments experienced double digit growth compared to the prior year period. This growth is a result of sales of all our non-COVID product lines starting to return to pre-pandemic levels. Other revenues for the three months ended June 30, 2021 increased 102% to $1.9 million from $922,000 for the three months ended June 30, 2020 due to increased research and development funding for the development of our COVID-19 tests and our HIV medication adherence tests and higher royalty income.

Consolidated net revenues derived from products sold to customers outside of the United States were $10.0 million and $7.3 million, or 17% and 25% of total net revenues, in the three months ended June 30, 2021 and 2020, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

Diagnostics Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our Diagnostics segment during the three months ended June 30, 2021 and 2020.

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2021	2020	% Change	2021	2020
Infectious disease testing	$ 15,623	$ 8,737	79 %	81 %	84 %
Risk assessment testing	2,629	1,533	71	14	15
Net product revenues	18,252	10,270	78	95	99
Other	1,059	157	575	5	1
Net revenues	$ 19,311	$ 10,427	85 %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 79% to $15.6 million for the three months ended June 30, 2021 from $8.7 million for the three months ended June 30, 2020. This increase resulted from higher world-wide OraQuick® HIV and HCV product sales.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the three months ended June 30, 2021 and 2020.

	Three Months Ended June 30,		
Market	2021	2020	% Change
Domestic HIV	$ 4,135	$ 3,197	29 %
International HIV	6,809	3,883	75
Net HIV revenues	10,944	7,080	55
Domestic HCV	2,571	757	240
International HCV	1,729	641	170
Net HCV revenues	4,300	1,398	208
Net OraQuick® revenues	$ 15,244	$ 8,478	80 %

Domestic OraQuick® HIV sales increased 29% to $4.1 million for the three months ended June 30, 2021 from $3.2 million for the three months ended June 30, 2020. This increase was primarily the result of higher sales of our OraQuick® In-Home HIV test as a result of Centers for Disease Control and Prevention ("CDC") guidance recommending the use of an OTC product for testing in lieu of in-person testing as a result of the COVID-19 pandemic and the re-opening of physician offices and clinics for HIV testing during the current quarter.

International sales of our OraQuick® HIV tests increased 75% to $6.8 million for the three months ended June 30, 2021 from $3.9 million for the three months ended June 30, 2020. This increase was primarily due to customer ordering patterns of our HIV Self-Test in Africa.

Domestic OraQuick® HCV sales increased 240% to $2.6 million for the three months ended June 30, 2021 from $757,000 for the three months ended June 30, 2020, due to the re-opening of testing programs closed as a result of the COVID-19 pandemic and as resources used for COVID-19 testing and vaccinations were redirected back to HCV testing.

International OraQuick® HCV sales increased 170% to $1.7 million for the three months ended June 30, 2021 from $641,000 for the three months ended June 30, 2020 as sales into certain international markets started to return back to pre-pandemic levels.

Risk Assessment Market

Sales to the risk assessment market increased 71% to $2.6 million for the three months ended June 30, 2021 compared to $1.5 million for the three months ended June 30, 2020 due to hiring increases driven by the economic recovery from the COVID-19 pandemic.

Other Revenues

Other revenues for the three months ended June 30, 2021 increased to $1.1 million from $157,000 for the three months ended June 30, 2020, largely due to research and development funding for our COVID-19 and HIV medication adherence tests, which was not present in the prior year period, and the inclusion of royalty income under the terms of a new licensing agreement related to our proprietary buffer solution used for the preservation and stabilization of oral fluid specimens.

Molecular Solutions Segment

The table below shows a breakdown of our total net revenues (dollars in thousands) during the three months ended June 30, 2021 and 2020.

	Three Months Ended June 30,		
Market	**2021**	**2020**	**% Change**
Genomics	$ 19,582	$ 6,471	203 %
Microbiome	2,853	853	234
COVID-19	11,491	8,472	36
Laboratory services	3,114	2,103	48
Other product and service revenues	449	168	167
Net molecular product and services revenues	$ 37,489	$ 18,067	107
Other	807	765	5
Net molecular product and services revenues	$ 38,296	$ 18,832	103 %

Sales of our genomics products increased 203% to $19.6 million for the three months ended June 30, 2021 compared to $6.5 million for the three months ended June 30, 2020, as we started to see our customer's businesses recover from the COVID-19 pandemic.

Microbiome kit sales increased 234% to $2.9 million for the three months ended June 30, 2021 compared to $853,000 for the three months ended June 30, 2020, also largely a result of the recovery in the market from the COVID-19 pandemic.

Sales of our molecular sample collection kits for COVID-19 testing increased to $11.5 million for the three months ended June 30, 2021 compared to $8.5 million during the comparable period in 2020 due to increased demand since the pandemic began late in the first quarter of 2020. However, we are seeing demand for molecular COVID-19 testing during the second quarter of 2021 begin to decline sequentially primarily due to the availability of vaccines and this trend is expected to continue in future periods.

Laboratory services revenues increased 48% to $3.1 million for the three months ended June 30, 2021 compared to $2.1 million for the three months ended June 30, 2020, due to customers resuming activities delayed by the COVID-19 pandemic.

Other revenues for the three months ended June 30, 2021 increased 5% to $807,000 from $765,000 the three months ended June 30, 2020, largely as a result of higher royalty income under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 53% for the three months ended June 30, 2021 compared to 59% for the three months ended June 30, 2020. This decrease is due to lower funding that subsidizes the international sale of our HIV Self-Test under the charitable support agreement with the Gates Foundation and higher scrap and manufacturing costs. The Gates agreement and the subsidy provided thereunder expired on June 30, 2021.

Consolidated operating income for the three months ended June 30, 2021 was $1.8 million, an $11.2 million increase from the $9.4 million operating loss reported for the three months ended June 30, 2020. Results for the three months ended June 30, 2021 were positively impacted by the increase in revenues dollars partially offset by lower gross profit percentages and an increase spending in operating expenses.

OPERATING INCOME (LOSS) BY SEGMENT

We evaluate performance of our operating segments based on revenue and operating income. Reportable segments have no inter-segment revenue and inter-segment expenses are eliminated in consolidation, including the fees associated with an intercompany service agreement between Diagnostics and Molecular Solutions.

Diagnostics Segment

The gross profit percentage for the Diagnostics segment was 34% for the three months ended June 30, 2021 compared to 42% for the three months ended June 30, 2020. This decrease is due to an increase in scrap costs, lower absorption of labor and fixed overhead costs as we built capacity in advance of the sale of our COVID-19 antigen test, and lower funding under the charitable support agreement with the Gates Foundation partially offset by the increase in other revenues which contribute 100% to our gross profit percentage and an improvement in product mix due to increased sales of higher gross profit percentage products.

Research and development expenses increased 16% to $5.0 million for the three months ended June 30, 2021 from $4.3 million for the three months ended June 30, 2020, largely due to higher staffing costs as a result of increased headcount to support COVID product development and the inclusion of employees from the UrSure acquisition which occurred in July 2020. Sales and marketing expenses were $6.6 million for both the three months ended June 30, 2021 and 2020. General and administrative expenses increased 2% to $7.1 million for the three months ended June 30, 2021 from $7.0 million for the three months ended June 30, 2020 largely due to higher staffing and consulting costs offset by lower legal and accounting fees.

All of the above contributed to the Diagnostics segment's operating loss of $11.9 million for the three months ended June 30, 2021, which included non-cash charges of $939,000 for depreciation and amortization and $1.4 million for stock-based compensation. The Diagnostics segment operating loss also included a non-cash pre-tax benefit of $220,000 associated with the change in the fair value of acquisition-related contingent consideration.

Molecular Solutions Segment

The gross profit percentage for the Molecular Solutions segment was 63% for the three months ended June 30, 2021 compared to 68% for the three months ended June 30, 2020. This decrease is attributable to an increase in third party manufacturing costs at our subcontractors and a change in product mix of increased sales of lower gross profit product.

Research and development expenses increased 3% to $2.7 million for the three months ended June 30, 2021 from $2.6 million for the three months ended June 30, 2020 due to the timing of spending on laboratory services and microbiome projects. Sales and marketing expenses increased 10% to $3.9 million for the three months ended June 30, 2021 from $3.5 million for the three months ended June 30, 2020 due to higher staffing costs partially offset by a decrease in our reserve for uncollectible accounts. General and administrative expenses increased 18% to $3.9 million for the three months ended June 30, 2021 from $3.3 million for the three months ended June 30, 2020 due to increased staffing costs and higher legal fees.

All of the above contributed to the Molecular Solutions segment's operating income of $13.7 million for the three months ended June 30, 2021, which included $1.7 million for depreciation and amortization and $113,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established against our total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended June 30, 2021, a U.S. state tax benefit of $54,000 was recorded compared to $9,000 of state income tax expense recorded for the three months ended June 30, 2020. For the three months ended June 30, 2021, foreign tax expense of $3.7 million was recorded compared to foreign tax expense of $1.3 million recorded for the three months ended June 30, 2020. The overall increase in tax expense is largely a result of the increase in income before taxes generated by our Canadian subsidiary.

Six months ended June 30, 2021 compared to June 30, 2020

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the six months ended June 30, 2021 and 2020.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2021	2020	% Change	2021	2020
Diagnostics	$ 31,585	$ 27,933	13 %	27 %	46 %
Molecular Solutions	80,735	31,290	158	69	51
Net product and services revenues	112,320	59,223	90	96	97
Other	3,869	1,632	137	4	3
Net revenues	$ 116,189	$ 60,855	91 %	100 %	100 %

Consolidated net product and services revenues increased 90% to $112.3 million for the six months ended June 30, 2021 from $59.2 million for the comparable period of 2020. Higher sales of our molecular sample collection kits for COVID-19 testing, commercial genomics products, microbiome kits, domestic OraQuick® HIV tests, and domestic and international OraQuick® HVC tests and higher revenues from laboratory services were partially offset by lower sales of our international OraQuick® HIV Self-Tests. Other revenues for the six months ended June 30, 2021 increased 137% to $3.9 million from $1.6 million for the six months ended June 30, 2020 due to increased research and development funding for the development of our COVID-19 tests and our HIV medication adherence tests and higher royalty income.

Consolidated net revenues derived from products sold to customers outside of the United States were $19.5 million and $17.3 million, or 17% and 28% of total net revenues, in the first six months of 2021 and 2020, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total consolidated net revenues.

Net Revenues by Segment

Diagnostics Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our Diagnostics segment during the six months ended June 30, 2021 and 2020.

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2021	2020	% Change	2021	2020
Infectious disease testing	$ 26,994	$ 23,400	15 %	80 %	83 %
Risk assessment testing	4,591	4,533	1	14	16
Net product revenues	31,585	27,933	13	94	99
Other	2,272	286	694	6	1
Net revenues	$ 33,857	$ 28,219	20 %	100 %	100 %

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 15% to $27.0 million for the six months ended June 30, 2021 from $23.4 million for the six months ended June 30, 2020. This increase resulted from higher domestic sales of our OraQuick® HIV and HCV products and higher international OraQuick® HVC product sales partially offset by lower sales of our international OraQuick® HIV Self-Tests.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the six months ended June 30, 2021 and 2020.

	Six Months Ended June 30,		
Market	2021	2020	% Change
Domestic HIV	$ 9,050	$ 7,414	22 %
International HIV	10,672	10,832	(1)
Net HIV revenues	19,722	18,246	8
Domestic HCV	3,754	2,251	67
International HCV	2,914	1,738	68
Net HCV revenues	6,668	3,989	67
Net OraQuick® revenues	$ 26,390	$ 22,235	19 %

Domestic OraQuick® HIV sales increased 22% to $9.0 million for the six months ended June 30, 2021 from $7.4 million for the six months ended June 30, 2020. This increase was primarily the result of higher sales of our OraQuick® In-Home HIV test as a result of CDC guidance recommending the use of an OTC product for testing in lieu of in-person testing due to the COVID-19 pandemic.

International sales of our OraQuick® HIV tests decreased 1% to $10.7 million for the six months ended June 30, 2021 from $10.8 million for the six months ended June 30, 2020 largely due to the timing of customer orders.

Domestic OraQuick® HCV sales increased 67% to $3.8 million for the six months ended June 30, 2021 from $2.3 million for the six months ended June 30, 2020 due to the re-opening of testing programs closed as a result of the COVID-19 pandemic and as resources used for COVID-19 testing and vaccinations were redirected back to HCV testing.

International OraQuick® HCV sales increased 68% to $2.9 million for the six months ended June 30, 2021 from $1.7 million for the six months ended June 30, 2020 as sales into certain international markets are returning to pre-pandemic levels.

Risk Assessment Market

Sales to the risk assessment market increased 1% to $4.6 million for the six months ended June 30, 2021 compared to $4.5 million for the six months ended June 30, 2020 due to hiring increases driven by the economic recovery from the COVID-19 pandemic.

Other Revenues

Other revenues for the six months ended June 30, 2021 increased to $2.3 million from $286,000 for the six months ended June 30, 2020, largely due to research and development funding for our COVID-19 and HIV medication adherence tests, which was not present in the prior year period, and the inclusion of royalty income under the terms of a new licensing agreement related to our proprietary buffer solution used for the preservation and stabilization of oral fluid specimens.

Molecular Solutions Segment

The table below shows a breakdown of our total net revenues (dollars in thousands) during the six months ended June 30, 2021 and 2020.

	Six Months Ended June 30,			
Market	**2021**	**2020**	**% Change**	
Genomics	$ 30,646	$ 14,863	106	%
Microbiome	4,941	2,430	103	
COVID-19	38,880	8,866	339	
Laboratory services	5,611	4,517	24	
Other product revenues	657	614	7	
Net molecular product and services revenues	$ 80,735	$ 31,290	158	
Other	1,597	1,346	19	
Net molecular product and services revenues	$ 82,332	$ 32,636	152	%

Sales of our genomics products increased 106% to $30.6 million for the six months ended June 30, 2021 compared to $14.9 million for the six months ended June 30, 2020 as we start to see our customer's businesses recover from the COVID-19 pandemic and due to strong organic growth from customers in the commercial animal markets.

Microbiome kit sales increased 103% to $4.9 million for the six months ended June 30, 2021 compared to $2.4 million for the six months ended June 30, 2020 due to a recovery in the market from the COVID-19 pandemic.

Sales of our molecular sample collection kits for COVID-19 testing increased to $38.9 million for the six months ended June 30, 2021 compared to $8.9 million during the comparable period in 2020 due to increased demand as the COVID-19 pandemic began late in the first quarter of 2020.

Laboratory services revenues increased 24% to $5.6 million for the six months ended June 30, 2021 compared to $4.5 million for the six months ended June 30, 2020, due to customers resuming activities delayed by the COVID-19 pandemic.

Other revenues for the six months ended June 30, 2021 increased 19% to $1.6 million from $1.3 million for the six months ended June 30, 2020 largely as a result of higher royalty income under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 59% for the six months ended June 30, 2021 compared to 55% for the six months ended June 30, 2020. Gross profit percentage for the six months ended June 30, 2021 benefited from an improved product mix associated with an increase in higher gross profit percentage product sales and the increase in other revenues which contribute 100% to our gross profit percentage partially offset by lower absorption of labor and fixed over-head costs as we build capacity in advance of sales of the COVID-19 antigen test, lower funding under the charitable support agreement with the Gates Foundation, and an increased scrap expense.

Consolidated operating income for the six months ended June 30, 2021 was $12.2 million, a $29.6 million increase from the $17.4 million operating loss reported for the six months ended June 30, 2020. Results for the six months ended June 30, 2021 were positively impacted by the

increased revenues and the inclusion of an $1.0 million non-cash benefit related to the fair value change in acquisition-related contingent consideration partially offset by the lower gross profit percentage and increased operating expenses.

OPERATING INCOME (LOSS) BY SEGMENT

We evaluate performance of our operating segments based on revenue and operating income. Reportable segments have no inter-segment revenue and inter-segment expenses are eliminated in consolidation, including the fees associated with an intercompany service agreement between Diagnostics and Molecular Solutions.

Diagnostics Segment

The gross profit percentage for the Diagnostics segment was 38% for the six months ended June 30, 2021 compared to 43% for the six months ended June 30, 2020. This decrease is due lower absorption of labor and fixed overhead costs as we built capacity in advance of sales of the COVID-19 antigen test, lower funding under the charitable support agreement with the Gates Foundation and, increased scrap costs partially offset by an increase in other revenues which contribute 100% to our gross profit percentage and an improvement in product mix due to increased sales of higher gross profit percentage products.

Research and development expenses increased 49% to $11.6 million for the six months ended June 30, 2021 from $7.8 million for the six months ended June 30, 2020, largely due to increased spending associated with COVID-19 product development and higher staffing costs. Sales and marketing expenses increased 14% to $12.8 million for the six months ended June 30, 2021 from $11.2 million for the six months ended June 30, 2020, due to higher market research, consulting and advertising spending to prepare for the sale of the COVID-19 rapid antigen tests partially offset by a lower reserve adjustment for uncollectible accounts. General and administrative expenses decreased 5% to $13.6 million for the six months ended June 30, 2021 from $14.3 million for the six months ended June 30, 2020 due to lower legal fees and increased intercompany service fees allocated to the Molecular Solutions segment, partially offset by increased staffing costs.

All of the above contributed to the Diagnostics segment's operating loss of $24.1 million for the six months ended June 30, 2021, which included non-cash charges of $1.8 million for depreciation and amortization and $2.7 million for stock-based compensation. The Diagnostics segment operating loss also included a non-cash pre-tax benefit of $1.0 million associated with the change in the fair value of acquisition-related contingent consideration.

Molecular Solutions Segment

The gross profit percentage for the Molecular Solutions segment was 68% for the six months ended June 30, 2021 compared to 65% for the six months ended June 30, 2020. This increase is due to higher gross profit percentage product sales partially offset by increased manufacturing costs at our third party contract manufacturers.

Research and development expenses increased 7% to $5.1 million for the six months ended June 30, 2021 from $4.8 million for the six months ended June 30, 2020 due to increased spending associated with projects within our laboratory services business. Sales and marketing expenses increased 15% to $7.2 million for the six months ended June 30, 2021 from $6.3 million for the six months ended June 30, 2020 due to higher staffing costs. General and administrative expenses increased 25% to $7.6 million for the six months ended June 30, 2021 from $6.1 million for the six months ended June 30, 2020 due to increased intercompany service fees allocated from the Diagnostics segment, estimated penalties incurred on delinquent sales tax filings that were not incurred in the prior year period, and higher staffing costs.

All of the above contributed to the Molecular Solutions segment's operating income of $36.3 million for the six months ended June 30, 2021, which included $3.3 million for depreciation and amortization and $195,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established against our total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the six months ended June 30, 2021, U.S. state tax expense of $115,000 was recorded compared to $18,000 of state income tax expense recorded for the six months ended June 30, 2020. For the six months ended June 30, 2021, foreign tax expense of $10.0 million was recorded compared to foreign tax expense of $2.0 million recorded for the six months ended June 30, 2020. The overall increase in tax expense is largely a result of the increase in income before taxes generated by our Canadian subsidiary.

Liquidity and Capital Resources

	June 30, 2021	December 31, 2020
	(In thousands)	
Cash and cash equivalents	$ 158,120	$ 160,802
Available for sale securities	71,316	96,317
Working capital	238,478	242,404

Our cash and cash equivalents and available-for-sale securities decreased to $229.4 million at June 30, 2021 from $257.1 million at December 31, 2020. Our working capital decreased to $238.5 million at June 30, 2021 from $242.4 million at December 31, 2020.

During the six months ended June 30, 2021, net cash used in operating activities was $3.5 million. Our net income of $2.4 million included non-cash charges for depreciation and amortization expense of $5.1 million, stock-based compensation expense of $2.9 million, a provision for doubtful accounts of $747,000, and other non-cash benefits of $167,000. Operating activities also included a benefit for the change in the estimated fair value of acquisition-related contingent consideration of $1.0 million and a $142,000 contingent consideration payment representing the excess of the total contingent consideration payment made during the six months ended June 30, 2021 over the fair value of the liability estimated at the time of acquisition. Sources of cash generated from our working capital accounts included a $4.4 million increase in accounts payable due to the timing of invoice received and in payments, a $3.7 million decrease in accounts receivable as a result of the collection of large outstanding balances, and a $154,000 decrease in prepaid expenses and other assets. Offsetting these sources of cash were an increase in inventory of $16.1 million to meet anticipated demand to support COVID-19 testing programs, a decrease in accrued expenses and other liabilities of $4.9 million largely due to payment of our 2020 management incentive bonuses and payment of outstanding sales tax liabilities and a decrease in deferred revenue of $630,000 due to the recognition of customer prepayments.

Net cash provided by investing activities was $10.4 million for the six months ended June 30, 2021, which reflects proceeds from the maturities and redemptions of investments of $43.7 million offset by $22.9 million used to acquire property and equipment largely to increase our manufacturing capacity and $10.4 million used to purchase investments.

Net cash used in financing activities was $2.5 million for the six months ended June 30, 2021, which reflects $1.9 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares awarded to our employees, payments of lease liabilities of $510,000 and $264,000 used for payment of our contingent consideration obligation offset by proceeds from stock option exercises of $121,000.

We expect current balances of cash and cash equivalents and available-for-sale securities to be sufficient to fund our current and foreseeable operating and capital needs. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures including continued investment to expand our capacity to manufacture products for COVID-19 testing, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the timing and cost of future stock purchases, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, market acceptance of new products, competing technological and market developments, the impact of the current economic environment and other factors. In addition, $124.8 million or 54% of our $229.4 million in cash, cash equivalents and available-for-sale securities belongs to our Canadian subsidiary. Repatriation of such cash into the United States exceeding certain levels could have adverse tax consequences.

A summary of our obligations to make future payments under contracts existing at December 31, 2020 is included in Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2020. As of June 30, 2021, except as described in note 11 within the notes to the consolidated financial statements, there were no significant changes to this information.

Critical Accounting Policies and Estimates

This Management’s Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to the bad debts, customer sales returns, inventories, intangible assets, income taxes, revenue recognition, performance-based compensation, contingencies and litigation. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC. During the first six months of 2021, there were no material changes to our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, we have no material derivative risk to report under this Item.

As of June 30, 2021, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 5.6% of our total revenues for the six months ended June 30, 2021. We do have foreign currency exchange risk related to our operating subsidiaries in Canada and in Belgium. The principal foreign currencies in which we conduct business are the Canadian dollar and the Euro. Fluctuations in the exchange rate between the U.S. dollar and these foreign currencies could affect year-to-year comparability of operating results and cash flows. Our foreign subsidiaries had net assets, subject to translation, of $192.9 million in U.S. Dollars, which are included in the Company's consolidated balance sheet as of June 30, 2021. A 10% unfavorable change in the Canadian-to-U.S. dollar and Euro-to-U.S. dollar exchange rates would have decreased our comprehensive income by approximately $16.4 million in the six months ended June 30, 2021.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2021. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of June 30, 2021 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 was accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

From time to time, we are involved in certain legal actions arising in the ordinary course of business. In management's opinion, based upon the advice of counsel, the outcomes of such actions are not expected, individually or in the aggregate, to have a material adverse effect on our future financial position or results of operations.

Spectrum Patent Litigation

In March 2021, we filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain DNA saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum has filed an answer to the initial complaint, asserting that its device does not infringe our patent and that our patent is invalid. In August 2021, we amended our complaint to add a second patent to this litigation. We are seeking injunctive relief and damages in this matter.

Item 1A. RISK FACTORS

There have been no material changes to the risk factors disclosed in Item 1A, entitled "Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2020 and our Quarterly Report on form 10-Q for the quarter ended June 30, 2021.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Period	Total number of shares purchased		Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs [1, 2]
April 1, 2021 - April 30, 2021	261	[3]	$ 9.70	—	11,984,720
May 1, 2021 - May 31, 2021	15,077	[3]	9.62	—	11,984,720
June 1, 2021 - June 30, 2021	—		—	—	11,984,720
	15,338			—	

(1) On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to $25.0 million of outstanding shares. This share repurchase program may be discontinued at any time.

(2) This column represents the amount that remains available under the $25.0 million repurchase plan, as of the period indicated. We have made no commitment to purchase any shares under this plan.

(3) Pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted and performance shares, these shares were retired to satisfy minimum tax withholdings.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

None

Item 6. EXHIBITS

Exhibit Number	Exhibit
31.1*	Certification of Stephen S. Tang required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Roberto Cuca required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Stephen S. Tang required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Roberto Cuca required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the Instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page from the Company’s Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2021 has been formatted in Inline XBRL

*Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

/s/ Roberto Cuca

Date: August 5, 2021

Roberto Cuca
Chief Financial Officer
(Principal Financial Officer)

/s/Michele M. Miller

Date: August 5, 2021

Michele M. Miller
Vice President, Finance and Controller
(Principal Accounting Officer)

Exhibit 31.1

Certification

I, Stephen S. Tang, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2021

/s/Stephen S. Tang

Stephen S. Tang
President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

Certification

I, Roberto Cuca, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d – 15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2021

/s/ *Roberto Cuca*

Roberto Cuca
Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen S. Tang, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen S. Tang

Stephen S. Tang
President and Chief Executive Officer

August 5, 2021

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. § 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Roberto Cuca, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Roberto Cuca

Roberto Cuca
Chief Financial Officer

August 5, 2021